

REMARKS

Claims 16-19, 21, and 22 are currently pending. Claims 1-15 and 20 are canceled. New claims 21 and 22 are supported by the pending claims and paragraph [0019] of the application as originally filed.

Claim Rejections under 35 U.S.C. §102

Claim 15 was rejected under 35 U.S.C. § 102(b) as being anticipated by Yamasaki et al (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) as evidenced by Patel et al. (US Patent No. 4855294).

Claim 15 is canceled with this amendment, so this rejection is currently moot.

Claim Rejections --35 USC Sec. § 103

Claims 11, 13, and 16-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) in view of Hirashima et al. (US Patent No. 6471984) and as evidenced by Patel et al. (US Patent No. 4855294).

Claims 11, 13, and 20 have been canceled in this amendment.

In rebuttal to the arguments presented in the November 29, 2010 response, the examiner note that McPeak et al. patent notes at column 16, lines 66-67:

“The preferred counterirritants include, but are not limited to, glycerol, corticosteroids and salicylates.”

However, applicants note that McPeak et al also describes the following at column 15, lines 48-55:

“When aqueous suspensions and/or elixirs are desired for oral administration ...together with such **diluents** as water, ethanol, propylene

glycol, **glycerin** and various combinations thereof.” (Emphasis added).

Clearly glycerin, as is known in the art, has many different properties and uses depending on the circumstances.

More importantly, with regard to the Yamasaki et al. reference, glycerin is described and used as humectant, not as a counterirritant. At column 4, lines 13-29, Yamasaki et al. state:

Examples of the humectant according to the present invention include polyhydric alcohols such as ethylene glycol, diethylene glycol, polyethylene glycol, **glycerin**, sorbitol... These humectants are employed to maintain the water content in the adhesive gel base at a constant level, so that the adverse effect on the drug releasing rate to the skin, resulting from the evaporation of the water from the obtained external skin patch during its storage or use, can be reduced. ...

(Emphasis added)

Consequently, it would not be obvious to one skilled in the art to replace the humectant in Yamasaki et al. with a counterirritant, no matter how one classifies glycerin. A person skilled in the art is only taught a local anesthetic and antiphlogistic analgesic agent in a patch that also includes a humectant. There is no link to a counter-irritant of any kind.

Hirashima et al. and Patel were discussed previously in prior amendments, but the arguments are incorporated herein. However, these arguments are less material since Yamasaki et al. calls for humectant in its composition, not a counter-irritant. One skilled in the art would not look to counter-irritants to replace a humectant in the Yamasaki et al. reference.

Claims 11, 13, and 16-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) and further in view of Bernstein (US Patent No. 4997853 and as evidenced by Patel et al. (US Patent No. 4855294).

Claims 11, 13, and 20 have been canceled in this amendment. Claims 16-19 and new dependent claims 21 and 22 have been amended to only include larger amounts of capsaicin, larger than those suggested by Bernstein, greater than 1.0 up to 5 wt%.

Yamasaki et al and Patel have already been discussed in depth. Bernstein only discloses capsaicin; there is no mention or suggestion of l-menthol, dl-menthol, dl-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil, eucalyptus oil, or and nonyllic vanillylamide, nor the suggestion of using up to 5 wt%¹ of capsaicin. The largest amount of capsaicin suggested in Bernstein is 1 wt% (see claim 5 and column 1, line 42 of the Bernstein reference).

Applicants respectfully submit that the claims as presented are in condition for allowance.

¹ The undersigned incorrect wrote 20 wt% instead of 5 wt% in the last amendment. The undersigned apologizes for any confusion that error may have caused.

CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.

Respectfully submitted,

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